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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/330,903	06/11/1999	IGOR GONDA	6513/061US1	9995

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EXAMINER

SCHNIZER, RICHARD A

ART UNIT PAPER NUMBER

1635

DATE MAILED: 10/18/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/330,903

Applicant(s)

GONDA ET AL.

Examiner

Richard Schnizer, Ph. D

Art Unit

1635

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 03 August 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 58-64 and 66-73 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 58-64 and 67-73 is/are rejected.
- 7) ☒ Claim(s) 66 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>8/2/04</u> . | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

An amendment was received and entered on 8/3/05. Claim 73 was added as requested.

Claims 58-64 and 66-73 are pending and under consideration in this Office Action.

### ***Drawings***

The drawings submitted 8/3/05 are acceptable for examination.

### ***Priority***

This Application claims priority to application number 08/752,946, filed 11/21/96. This application issued as US Patent 5,906,202. The specification should be amended to reflect this status. Note also that for benefit claims under 35 U.S.C. 120, 121, or 365(c), the reference to 08/752,946 must include the relationship (i.e., continuation, divisional, or continuation-in-part) of the application.

Instant claims 57-64, and 66-71 recite a polynucleotide and a condensing agent. There is no support for this limitation in US Patent 5,906,202. Furthermore, '202 provides no support for the genus of negatively charged phospholipids recited in the instant claims. For these reasons, the priority date for the instant claims is considered to be that of provisional application 60/089,146 which is 6/12/98. Applicant's remarks regarding the priority date are addressed below at pages 14 and 15 under 35 USC 103 rejections.

***Rejections/Objections Withdrawn***

The rejection of claims 61, 62, and 72 for new matter, and claims 58-64 and 66-72 for lack of enablement, are is withdrawn in view of Applicant's amendments.

The previous art rejections of record are withdrawn in favor of new grounds of rejection more appropriately addressing the claims as amended, in particular the new requirement for negatively charged phospholipids.

Applicant's amendment was sufficient to overcome the objection to claim 72.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 64 and 73 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 64 is indefinite because it recites "the condensed polynucleotides" without antecedent basis.

Claim 73 is indefinite because the metes and bounds of "fusogen" are unclear. The term "fusogen" is used in the claim as if it referred to a single compound. However, "fusogen", in the context of lipidic delivery vehicles, generally refers to fusogenic lipids (such as DOPE) or fusogenic peptides such as hemagglutinin. It is unclear to what the claim is limited because the term is not defined in the specification.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The following rejections each cite the Schuster reference, US Patent 5,906,202, issued 5/25/99, which has an inventor in common with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). For applications filed on or after November 29, 1999, this rejection might also be overcome by showing that the subject matter of the reference and the claimed invention were, at the time the invention was made, owned

by the same person or subject to an obligation of assignment to the same person. See MPEP § 706.02(I)(1) and § 706.02(I)(2).

Because Applicant has filed a terminal disclaimer over US Patent 5,906,202, the '202 patent will be disqualified as prior art if Applicant files an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104.

Claims 58-62 and 70-72 are rejected under 35 U.S.C. 103(a) as being unpatentable over Debs et al (US Patent 5,756,353, issued 5/26/98) in view of Schuster et al (US Patent 5,906,202, issued 5/25/99) and Radhakrishnan (US Patent 5,049,389, issued 9/17/91).

Debs taught a method of targeting an area of a patient's respiratory tract by delivering to the patient an aerosol comprising particles of DNA condensed with cationic lipids. See abstract; column 10, lines 53-65; and column 12, lines 25-47. The size of the aerosol particles is adjusted based on the intended delivery site within the respiratory tract. A size range of from 0.5-5 microns is suggested for alveoli, and a size range of 4-12 microns is suggested for airway delivery. See column 12, lines 51-56, 60, and 61; and claims 1, and 14-16. Debs also taught that the cationic lipids could comprise dioleoylphosphatidylcholine (DOPC), dioleoylphosphatidylethanolamine (DOPE), and anionic lipids such as dioleoylphosphatidylglycerol. See column 11, lines 12-22.

Debs did not teach a method of controlling the patient's inhaled volume of aerosolized formulation and aerosol-free air.

Schuster taught a device and method of delivering a volume of aerosol to a target area of a lung. The method comprises measuring a volume of particle-free air inhaled into the lungs, drawing a measured volume of aerosol into the respiratory tract, and inhaling an additional volume of particle-free air, insufficient to fill the upper region of the patient's respiratory tract. Each of these three inhalation volumes is controlled. See e.g. claim 3 at column 38. Schuster teaches the delivery of gene vectors in carriers by this method. See column 2, line 33; paragraph bridging columns 7 and 8; paragraph bridging columns 30 and 31, and claims 11-13. The method involves adjusting the size of aerosol particles during delivery. Schuster teaches using aerosol particle sizes from 1-10 microns in aerodynamic diameter, and the adjustment of particle size in order to target specific regions of lung. See item c of claim 1; column 12, lines 37, 38, and 47-49; column 20, lines 30-50; and paragraph bridging columns 20 and 21. Schuster also teaches adjusting inspiratory flow rate to 0.2 to 3 liters per second. See claim 14; and column 12, lines 34-36. Note that the instant specification at page 27, lines 17-19 states that the device of Schuster is useful for the instant method. Note also that the specification states in that same passage that the Schuster patent was commonly owned at the time of filing (see double patenting rejections below). Under 35 USC 103 (a) and (c), the Schuster patent is considered prior art because the instant Application was filed prior to 11/29/1999.

Radhakrishnan taught that depth of penetration of aerosol particles into the respiratory tract is inversely related to the aerodynamic diameter of the particles, and discloses what size particles will reach various parts of the lung. See e.g. Fig. 3.

It would have been obvious to one of ordinary skill in the art at the time of the invention to use the device of Schuster to deliver the particles of Debs to the lung. One would have been motivated to do so because the device of Schuster, in addition to allowing targeting by adjustment of particle size, also improves the uniform deposition of particles on lung tissue by adjusting the volume of aerosol and aerosol free air released, and releasing at a desired point in the patient's inspiratory flow cycle. See column 4, lines 30-34. Note that Schuster taught the entire range of aerosol particle sizes recited in the instant claims, and it was well-recognized in the prior art, in view of Debs, Radhakrishnan, and Schuster that different areas of the respiratory tract were targeted by different sized aerosol particles. It would have been obvious to adjust the size of aerosol particles to particular aerodynamic diameters in order to target various sites in the respiratory tract, because Debs suggests that this should be done. The size of the particles is clearly a result effective variable, the optimization of which is routine in the art particularly in view of Radhakrishnan who established the relationship between particle size and depth of penetration into the respiratory tract.

Thus the invention as a whole was prima facie obvious.

Claims 58-63 and 67-72 are rejected under 35 U.S.C. 103(a) as being unpatentable over Debs et al (US Patent 5,756,353, issued 5/26/98) in view of Lee et al



(US Patent 5,908,777), Schuster et al (US Patent 5,906,202, issued 5/25/99), and Radhakrishnan (US Patent 5,049,389, issued 9/17/91).

Debs taught a method of targeting an area of a patient's respiratory tract by delivering to the patient an aerosol comprising particles of DNA condensed with cationic lipids. See abstract; column 10, lines 53-65; and column 12, lines 25-47. The size of the aerosol particles is adjusted based on the intended delivery site within the respiratory tract. A size range of from 0.5-5 microns is suggested for alveoli, and a size range of 4-12 microns is suggested for airway delivery. See column 12, lines 51-56, 60, and 61; and claims 1, and 14-16. Debs also taught that the cationic lipids could comprise dioleoylphosphatidylcholine (DOPC) and/or dioleoylphosphatidylethanolamine (DOPE). See column 11, lines 12-22.

Debs did not teach polycationic condensing agents such polylysine, spermine, and spermidine, or a method of controlling a patient's inhaled volume of aerosolized formulation and aerosol-free air.

Lee taught that DNA/cationic lipid complexes are cytotoxic, and appear incompatible with the physiological environment in vivo which is rich in anionic molecules, and that cationic lipids may have undesirable non-specific interactions with negatively charged serum components, blood cells, and the extracellular matrix in vivo. Lee addressed this problem by inventing lipidic particles comprising polycation-condensed nucleic acids complexed with anionic lipids, such as phosphatidylserine (PS). See abstract; column 1, lines 39-45; column 3, lines 21-27; and column 6, line 61 to column 7, line 7. Lee also taught the use of a variety of polycation condensing

agents including: polylysine, protamine, spermine, and spermidine. See column 5, lines 48-57. Lee exemplified negatively charged liposomes comprising PS and DOPE. See column 6, lines 61-64.

Schuster taught a device and method of delivering a volume of aerosol to a target area of a lung. The method comprises measuring a volume of particle-free air inhaled into the lungs, drawing a measured volume of aerosol into the respiratory tract, and inhaling an additional volume of particle-free air, insufficient to fill the upper region of the patient's respiratory tract. Each of these three inhalation volumes is controlled. See e.g. claim 3 at column 38. Schuster teaches the delivery of gene vectors in carriers by this method. See column 2, line 33; paragraph bridging columns 7 and 8; paragraph bridging columns 30 and 31, and claims 11-13. The method involves adjusting the size of aerosol particles during delivery. Schuster teaches using aerosol particle sizes from 1-10 microns in aerodynamic diameter, and the adjustment of particle size in order to target specific regions of lung. See item c of claim 1; column 12, lines 37, 38, and 47-49; column 20, lines 30-50; and paragraph bridging columns 20 and 21. Schuster also teaches adjusting inspiratory flow rate to 0.2 to 3 liters per second. See claim 14; and column 12, lines 34-36. Note that the instant specification at page 27, lines 17-19 states that the device of Schuster is useful for the instant method. Note also that the specification states in that same passage that the Schuster patent was commonly owned at the time of filing (see double patenting rejections below). Under 35 USC 103 (a) and (c), the Schuster patent is considered prior art because the instant Application was filed prior to 11/29/1999.

Radhakrishnan taught that depth of penetration of aerosol particles into the respiratory tract is inversely related to the aerodynamic diameter of the particles, and discloses what size particles will reach various parts of the lung. See e.g. Fig. 3.

It would have been obvious to one of ordinary skill in the art at the time of the invention to substitute the anionic lipidic delivery vehicles of Lee for the cationic lipids of Debs. One would have been motivated to do so in the reasonable expectation of obtaining enhanced transfection. See e.g. column 4, lines 56-66.

It would have been obvious to one of ordinary skill in the art at the time of the invention to use the device of Schuster to practice the invention of Debs as modified by Lee, above. One would have been motivated to do so because the device of Schuster, in addition to allowing precise targeting by adjustment of particle size, also improves the uniform deposition of particles on lung tissue by adjusting the volume of aerosol and aerosol free air released, and releasing at a desired point in the patient's inspiratory flow cycle. See column 4, lines 30-34. Note that Schuster taught the entire range of aerosol particle sizes recited in the instant claims, and it was well-recognized in the prior art, in view of Debs, Radhakrishnan, and Schuster that different areas of the respiratory tract were targeted by different sized aerosol particles. It would have been obvious to adjust the size of aerosol particles to particular aerodynamic diameters in order to target various sites in the respiratory tract, because Debs suggests that this should be done. The size of the particles is clearly a result effective variable, the optimization of which is routine in the art particularly in view of Radhakrishnan who establishes the relationship between particle size and depth of penetration into the respiratory tract.

Thus the invention as a whole was *prima facie* obvious.

Claims 63, 68, and 72 are rejected under 35 U.S.C. 103(a) as being unpatentable over Debs et al (US Patent 5,756,353, issued 5/26/98) in view of Lee et al (US Patent 5,908,777), Schuster et al (US Patent 5,906,202, issued 5/25/99), Radhakrishnan (US Patent 5,049,389, issued 9/17/91), and Chu et al (US Patent 6,030,834, issued 2/29/00).

The teachings of Debs, Lee, Schuster, and Radhakrishnan are discussed above and render obvious methods of targeting an area of a patient's respiratory tract comprising aerosolizing a formulation comprising anionic phospholipids and polynucleotides condensed with polycations, adjusting the aerodynamic diameter of the particles based on the targeted area of a patient's respiratory tract, and controlling the patient's inhaled volume of aerosolized formulation and aerosol-free air.

The combined references do not teach the use of protamine sulfate or putrescine as a condensing agent.

Chu taught that polycationic condensing agents include polylysine, polyarginine, polyornithine, protamine, spermine, spermidine, and putrescine. MPEP 2144.06 indicates that when it is recognized in the art that elements of an invention can be substituted, one for the other, while retaining essential function, such elements are art-recognized equivalents. An express suggestion to substitute one equivalent component or process for another is not necessary to render such substitution obvious. In re Fout, 675 F.2d 297, 213 USPQ 532 (CCPA 1982). Furthermore, MPEP 2144.07 indicates

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that the selection of a known material based on its suitability for its intended use supports the determination of prima facie obviousness. See also *Sinclair & Carroll Co. v. Interchemical Corp.*, 325 U.S. 327, 65 USPQ 297 (1945). In this case the prior art clearly considered putrescine and protamine sulfate to be equivalent to polylysine, spermine, and spermidine as a nucleic acid condensing agent.

Thus the invention as a whole was prima facie obvious.

Claims 64 and 69 are rejected under 35 U.S.C. 103(a) as being unpatentable over Debs et al (US Patent 5,756,353, issued 5/26/98), Lee et al (US Patent 5,908,777), Schuster et al (US Patent 5,906,202, issued 5/25/99), Radhakrishnan (US Patent 5,049,389, issued 9/17/91) and Chu et al (US Patent 6,030,834, issued 2/29/00), as applied to claims 63, 68, and 72 above, and further in view of the evidence of Tang et al (Gene Therapy, 4: 832-832, 1997).

The teachings of Debs, Lee, Schuster, Radhakrishnan, and Chu are discussed above and render obvious methods of targeting an area of a patient's respiratory tract comprising aerosolizing a formulation comprising polynucleotides condensed with polycations, such as protamine sulfate, adjusting the aerodynamic diameter of the particles based on the targeted area of a patient's respiratory tract, and controlling the patient's inhaled volume of aerosolized formulation and aerosol-free air.

These references are silent as to the size of the condensed polynucleotides, and did not teach polyethyleneimine as a condensing agent.

Tang taught that cationic nucleic acid condensing agents with diverse structures such as polylysine, polyethyleneimine, and fractured or intact polyamidoamine dendrimers, form toroidal particles on the order of about 20-80 nm when complexed with DNA plasmids, with the majority of particles being 43-67 nm. See abstract and Fig. 4 on page 832. The size of polycation-nucleic acid complexes is considered to be an inherent feature. In view of the teachings of Tang, polycations generally give DNA complexes in the range of 20-80 nm. Absent evidence to the contrary, protamine sulfate condenses DNA to a size in this range as well. It is also apparent from the teachings of Tang that polyethyleneimine is an art-recognized equivalent of polylysine as a DNA condensing agent, so it would have been obvious to substitute polyethyleneimine for polylysine. See MPEP 2144.06 and 2144.07.

Thus the invention as a whole was prima facie obvious.

### ***Response to Arguments***

Applicants arguments filed 8/3/05 have been considered as they apply to the grounds of rejection set forth above, but are not persuasive.

Applicant argues at page 7 of the response that the rejections have too many references, require too much picking and choosing from different portions of the references, and are overcome by the amendments. These arguments are moot because the amendments necessitated new grounds of rejection.

At page 8 of the response Applicant argues that the claimed invention shows unexpected results as evidenced by the Patil publication which discloses that anionic

lipid/DNA complexes are less toxic to cells than cationic lipid/DNA complexes. This is unpersuasive for two reasons. First, the Patil reference does not disclose complexes of condensed polynucleotides and negatively charged phospholipids as instantly claimed, and so it cannot provide evidence of unexpected results for the instant invention. Second, the relative toxicities of cationic polycation/DNA complexes and anionic polycation/DNA complexes were known in the prior art. See Lee above, who taught that cationic lipid/DNA complexes were toxic due to their positive charge, and had undesirable interactions with negatively charged serum components, blood cells, and extracellular matrix in vivo. See especially abstract; column 1, lines 39-45; and column 3, lines 21-27.

At page 5 of the response Applicant addresses the priority date of the instant application. Applicant submitted on 8/3/05 copies of the assignment of the present application, and that of the Schuster patent relied on above. Applicant stated that both the instant application and the Schuster patent are owned by the same entity, and that through the undersigned attorney, Applicant's declare that the ownership remains as indicated in the assignments.

This is unpersuasive as regards the effective priority date, and as a rebuttal of the obviousness rejections. As stated above, and in the previous Action, 35 USC 103(a) rejections based on the Schuster reference might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which

corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). For applications filed on or after November 29, 1999, this rejection might also be overcome by showing that the subject matter of the reference and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person. See MPEP § 706.02(I)(1) and § 706.02(I)(2). Applicant's response does not amount to a declaration as discussed above under 37 CFR 1.130, 1.131, or 1.132 as discussed above. For these reasons the response does not disqualify the Schuster reference.

### ***Conclusion***

No claim is allowed. Claim 66 is objected to as depending from a rejected claim but would be allowable if rewritten in independent form incorporating all of the limitations of claim 72.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within



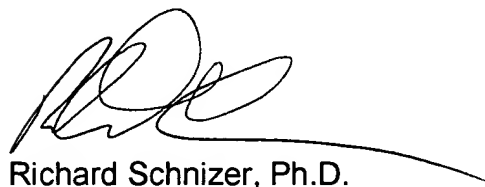
TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner(s) should be directed to Richard Schnizer, whose telephone number is 571-272-0762. The examiner can normally be reached Monday through Friday between the hours of 6:00 AM and 3:30 PM. The examiner is off on alternate Fridays, but is sometimes in the office anyway.

If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, Andrew Wang, can be reached at (571) 272-0811. The official central fax number is 571-273-8300. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

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Richard Schnizer, Ph.D.